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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,123	07/30/2001	Natalie Samantha Delany	PG3606USW	9804
20462	7590	05/09/2005	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			ANDRES, JANET L	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/857,123	DELANY ET AL.
	Examiner	Art Unit
	Janet L. Andres	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 February 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 and 6-51 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6-47 and 50 is/are withdrawn from consideration.
- 5) Claim(s) 1 and 3 is/are allowed.
- 6) Claim(s) 48,49 and 51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 14 February 2005 is acknowledged. Claims 1-4 and 6-51 are pending in this application. Claims 2, 4, 6-47, and 50 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification as containing hyperlinks is withdrawn in response to Applicant's amendment removing these hyperlinks.

3. The rejection of claims 1, 3, 48, and 49 under 35 U.S.C. 102(e) as anticipated by the '267 patent is withdrawn in response to Applicant's amendment limiting the claims to SEQ ID NO: 5 and the polypeptide encoding by SEQ ID NO: 4.

4. The rejection of claims 1, 3, 48, 49, and 51 under 35 U.S.C. 112, first paragraph, as lacking enablement for and written description of all hVR3 polypeptides and variants thereof is withdrawn in response to Applicant's amendment limiting these claims to SEQ ID NO: 5 and the polypeptide encoding by SEQ ID NO: 4.

5. The rejection of claims 1, 3, 48, 49, and 51 under 35 U.S.C 112, second paragraph, as indefinite in the recitation of "variants" is withdrawn in response to Applicant's amendment removing this term.

6. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as indefinite in the reference to a figure is withdrawn in response to Applicant's cancellation of this claim.

***Claim Rejections Maintained***

7. The rejection of claims 48 and 49 under 35 U.S.C. 112, first paragraph, as lacking enablement for the intended use in methods of screening is maintained for reasons of record in the office action of 14 October 2004 and newly applied to claim 51, which was omitted by typographical error in the previous office action.

Applicant argues that the specification indicates that the hVR3 polynucleotide is present in a number of tissues and that it has 49% homology with rat VR1. Applicant argues that the specification teaches numerous examples of hVR1 modulation and that based on the homology of human VR3 with rat VR1 the artisan would also expect hVR3 to be associated with the treatment of certain disorders wherein pain may be caused by inflammation.

Applicant's arguments have been fully considered but have not been found to be persuasive. The presence of the encoding polynucleotide in a number of tissues does not indicate what, if any, diseases it is associated with. It merely indicates that the encoding polynucleotide is present in the tissue. The limited homology with a murine protein equally does not serve to indicate to the skilled artisan that molecules that inhibit VR3 could be used to treat the many varieties of encompassed by the claims. There is no guidance that would allow the artisan to predict that any of these conditions could be affected by modulators of VR3, what is provided is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

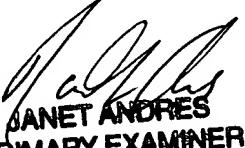
CLAIMS 1 AND 3 ARE ALLOWED. CLAIMS 48, 49, AND 51 ARE REJECTED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
29 April 2005



JANET ANDRES  
PRIMARY EXAMINER